

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:

see form PCT/ISA/220

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

31 JAN 2006

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No  
PCT/US2005/010206

International filing date (day/month/year)  
25.03.2005

Priority date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC  
A61M5/315

Applicant  
ELI LILLY AND COMPANY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/010206

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/010206

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims |      |
|                               | No: Claims  | 1-11 |
| Inventive step (IS)           | Yes: Claims |      |
|                               | No: Claims  | 1-11 |
| Industrial applicability (IA) | Yes: Claims | 1-11 |
|                               | No: Claims  |      |

2. Citations and explanations

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: WO 03/080160 A (ELI LILLY AND COMPANY; JUDSON, JARED, ALDEN; STEWART, WILLIAM, CHARLES) 2 October 2003 (2003-10-02)
- D2: US-A-6 086 567 (KIRCHHOFFER ET AL) 11 July 2000 (2000-07-11)
- D3: DE 39 00 926 A1 (DISETRONIC AG, BURGDORF, CH; DISETRONIC LICENSING AG, BURGDORF, CH) 17 August 1989 (1989-08-17)
- D4: DE 195 19 147 A1 (MEDICO DEVELOPMENT INVESTMENT CO., ASCONA, CH) 7 December 1995 (1995-12-07)
- D5: US 2003/050609 A1 (SAMS BERNARD) 13 March 2003 (2003-03-13)
- D6: US-A-5 114 405 (WINTER ET AL) 19 May 1992 (1992-05-19)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-11 is not new in the sense of Article 33(2) PCT.

2.1. The document D1 discloses (the references in parentheses applying to this document):

A medication dispensing apparatus (figs. 1-3) comprising:

a housing (28, 60);

a drive member within said housing and movable in a distal direction (62);

a fluid container defining a medicine-filled reservoir with a movable piston at one end and an outlet at the other end, said piston engageable by said drive member to be advanced toward said outlet a distance equal to a distal movement of said drive member when said drive member is moved distally (48, 52);

means for driving said drive member distally (64);

a latching element including a latching lip and a skid (74);

said drive member including an axially extending, skid-engaging surface along which said skid is slidable as said drive member passes distally during advancement, said skid-engaging surface having an axial length and a proximal end, said drive member along said axial length structured and arranged with said skid so as to maintain said latching lip against a spring force in a first position free of said driving means during dose preparing

and injecting prior to a final dose administration (74 rests against 62 until the last dose);  
and

wherein said skid-engaging surface shifts distally of said skid such that said skid passes beyond the proximal end upon administration of a final dose, whereby said latching lip is urged by said spring force from said first position to a second position to physically lock said driving means to prevent further dose preparing and injecting (74 contacts the last tooth on 62 after the last dose. In that position 64 cannot be moved any more because it is blocked against 82).

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

2.2. Also the documents D2-D6 (D2, figs. 1-2 & 4 items 1-2, 4, 12, 19-21, col. 5, lines 4-24; D3, figs. 1-10, items 4-5, 7, 13, 26-27, col. 3, lines 22-32; D4, fig. 8A, items 12, 14, 88, 90-91, col. 10, lines 17-28; D5, figs. 1-12, [0036], [0043], [0054], [0059]; D6, figs. 1-8, items 12, 28, 44, 46, 58) disclose the subject-matter of claim 1 (Article 33(2) PCT).

3. Dependent claims 2-11 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since they merely define trivial design options known in the art, see documents D1-D6 and the corresponding passages cited in the search report.

3.1. It seems that the idea of the application is to provide a medication dispensing apparatus with a repeat dosing facility having a latching element with a skid that falls down behind the drive member after the last dose and where at the same time a latching lip contacts and blocks the means for driving the drive member. With regard to the available prior art, it appears that if this idea would have been properly included into claim 1 it could have fulfilled the requirements of Article 33(1) PCT.

#### **Re Item VII**

#### **Certain defects in the international application**

4. Claim 1 is not drafted in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).

5. A document representing the closest prior art is not mentioned in the description (Rule 5.1(a)(ii) PCT).

**Re Item VIII**

**Certain observations on the international application**

6. Claim 1 does not fulfill the requirements of Article 6 PCT for the following reasons: The claim defines a "means for driving said drive member distally" but later refers to a "driving means". It is not clear whether this refers to the same feature or if they represent to distinct features.